K000384

MAR - 6 2000

CooperVision

711 North Road
Scottsville, New York 14546
(716) 385-6810
Fax (716) 889-5688

## Summary of 510(k) Submission

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| **1. Submitter Name and Address** | CooperVision, Inc.<br>711 North Road<br>Scottsville, NY 14546<br>Phone: (716) 385-6810<br>FAX: (716) 889-5688 |
| **2. Contact person** | Bonnie Tsymbal<br>Phone: (716) 264-3210<br>FAX: (716) 889-5688 |
| **3. Name of Device** | • Trade Nameis Frequency 55, Frequency 55 Aspheric, Encore, Encore Toric, Onevue, and CooperFlex (methafilcon A) soft (hydrophilic) contact lenses.<br>• Common Name is Soft (hydrophilic) Contact Lens.<br>• Classification Code is 86LPL.<br>• FDA Classification is Class II. |
| **4. Predicate Device** | The predicate device is the cast-molded Frequency 55, Frequency 55 Aspheric, Encore, Encore Toric, Onevue and Cooperflex covered under K973063. |
| **5. Legally Marketed Device** | Same as Trade Name |
| **6. Description of the Device** | The Frequency 55, Frequency 55 Aspheric, Encore, Onevue and CooperFlex (methafilcon A) soft (hydrophilic) contact lenses are available as spherical lenses. The Encore Toric (methafilcon A) soft (hydrophilic) contact lenses are available as astigmatic (toric) lenses. The lens material, methafilcon A, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid. The lenses are tinted edge to edge for visibility purposes with the color additive, Reactive Blue No. 4.<br><br>The description of the device is identical to the description of the device cleared under K973063. |

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| **7. Intended Use** | The Frequency 55, Frequency 55 Aspheric, Encore, Onevue and CooperFlex are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.<br><br>Encore Toric lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less.<br><br><u>Frequent/Planned Replacement</u><br><br>When prescribed for Frequent/Planned Replacement Wear, The Frequency 55, Frequency 55 Aspheric, Encore, Encore Toric, Onevue and CooperFlex lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner.<br><br><u>Disposable Wear</u><br><br>When prescribed for Disposable Wear, the wearing time prescribed by the eye care practitioner is for daily wear (single use). Patients should be instructed to discard the lenses at each removal. |
| **8. Technological Characteristics** | The technological characteristics of methafilcon A lenses manufactured with the alternate process are the same as the predicate device tinted after hydration. |
| **9. Non-Clinical Tests** | A side by side comparison of the optical properties of the lenses produced using both process' support the claim of substantial equivalence. No physical properties or toxicology studies were conducted as there is no change in the chemical formulation of the methafilcon A material. |
| **10. Clinical Studies** | There is no change in the Technological Characteristics, Chemistry, parameters or properties of the lenses manufactured using the alternate process, therefore no clinical studies were performed. |
| **11. Conclusion** | The determination of substantial equivalence is based on the fact that the lenses manufactured by the alternate process are the same design, chemical composition, have the same indication for use and utilize the same packaging and sterilization process as the predicate device. The lenses also undergo similar specified process controls and sampling plans as the currently marketed device, therefore lenses manufactured by the alternate process do not raise any questions of the lens safety and effectiveness. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2000

Ms. Bonnie Tysmbal
Manager, Regulatory Affairs
Cooper Vision
711 North Road
Scottsville, New York 14546

Re: K000384
Trade Name: methafilcon A Daily Wear Soft Hydrophilic Contact Lenses
Regulatory Class: II
Product Code: 86 LPL
Dated: February 4, 2000
Received: February 7, 2000

Dear Ms. Bonnie Tysmbal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indication for Use Statement

**510(k) Number:** K

**Device Name:** Frequency 55
Frequency 55 Aspheric
Encore
Encore Toric
Onevue
CooperFlex

**Indication for Use:**

1. Frequency 55, Frequency 55 Aspheric, Encore, Onevue and CooperFlex are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

2. Encore Toric lenses are indicated for daily wear for the correction of refractive ametropia )myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less.

**Frequent/Planned Replacement Wear**

When prescribed for Frequent/Planned Replacement Wear, the Frequency 55, Frequency 55 Aspheric, Encore, Encore Toric, Onevue and CooperFlex lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner.

**Disposable Wear**

When prescribed for Disposable Wear, the wearing time prescribed by the eye care practitioner is for daily wear (single use). Patients should be instructed to discard the lenses at each removal.

**PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED**

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Prescription Use** ✓ **OR** **Over-The-Counter** _____
**(Per 21 CFR 801.109)**

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000384